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(71) Applicant *(for all designated States except US)*: UNIVERSITE DE MONTREAL [CA/CA]; Bureau de liaison Entreprises-Université, C.P. 6128, Succursale A, Montréal, Québec H3C 3J7 (CA).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: SINDERBY, Christer [CA/CA]; 12750, 27th avenue, Montreal, Quebec H1E 1Z9 (CA).

(74) Agents: DUBUC, Jean, H. et al.; Goudreau Gage Dubuc, The Stock Exchange Tower, Suite 3400, 800 Place Victoria, Montreal, Quebec H4Z 1E9 (CA).

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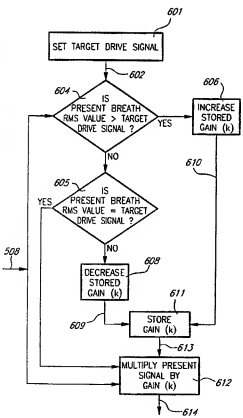

(57) Abstract: A gain controller and method for controlling the value of a gain is used in conjunction with an electrode array for detecting a signal representative of respiratory drive output of a patient during inspiration, and a lung ventilator for assisting inspiration of the patient. The gain controller comprises an input for receiving the signal representative of respiratory drive output; a comparator for determining whether the signal representative of respiratory drive output is higher or lower than a target drive signal; and a gain adjustment unit for increasing the value of a gain when the amplitude of the signal representative of respiratory drive output is higher than the amplitude of the target drive signal and for decreasing the value of this gain when the amplitude of the signal representative of respiratory drive output is lower than the amplitude of the target drive signal. The gain is applied to the signal representative of respiratory drive output to produce an amplified respiratory drive output representative signal used for controlling the lung ventilator. The advantage of target drive ventilation is that this mode of ventilation does not depend on pressure, flow or volume measurements. A leaky ventilatory line will introduce a change in respiratory drive to its target level. Also, changes in the patient's metabolic or patho-physiological status which result in altered respiratory drive will be compensated.

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TARGET DRIVE VENTILATION GAIN CONTROLLER AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the invention:

The invention relates to a target driven inspiratory assist ventilation system.

2. Brief description of the prior art:

The physiological mechanisms which generate myoelectrical activity when a muscle contracts have been known and understood for a long time. In particular, how to record signals from the muscles is one of the most extensively, theoretically described topics in physiology. Although the theoretical understanding is impressive, the bio-physiological application of these theories is, in practice, still deficient. As an example, no standardized analysis procedure has been developed for recording signals produced by activation of several, different motor units, the so called interference wave pattern. The interference wave pattern signal (EMG signal) contains an immense quantity of bio-physiological information about the given neuro-muscular function. However, as this EMG signal is very low in amplitude, it is sensitive to numerous artifacts. The influence of these artifacts varies in relation to the configuration of recording electrodes, the digitizing rate of the signal, and the type of recording technique.

Prior art analysis of interference wave pattern signals usually comprises a time consuming, tedious manual determination of the quality of the signal through visual inspection of this signal in the time domain. This determination is performed by a "subjective" investigator. Most of the prior art references describe how to calculate comparison estimates, but present very few comments on the signal quality. It is therefore not surprising to find that, in this technical field, independent studies evaluating the same questions have lead to different or even contradictory results.

Also in the prior art, the patient's inspiratory flow and volume has been used to control inspiratory proportional pressure assist ventilation. Proper adjustment of the relative contribution of flow and volume support during the inspiration requires knowledge of the elastic and viscous properties of the patient's respiratory system. Since the elastic and viscous properties may change, these measurements must be repeated at regular intervals. Correct and repeated measurements of elastance and resistance are difficult to set up in an intensive care unit. Moreover, in the presence of intrinsic positive end-expiratory pressure, the flow-volume controlled proportional assist ventilation may fail to trigger during whole breaths, and will definitively fail to trigger during at least the initial part of the inspiration which precedes the onset of flow; this period can last up to 300 ms in the case of a patient suffering from obstructive pulmonary disease. Finally leakage in the system will influence and may disturb the performance of the flow controlled proportional assist ventilation.

Traditionally, the goal of mechanical ventilation has been to maintain an optimal minute ventilation and respiratory load, and

therefore, has included specific measurements of inspiratory flow and tidal volume. New concepts in mechanical ventilation allow patients to take over the control of ventilatory support delivered, both in terms of magnitude and duration. New technology has also incorporated new methods of applying ventilatory assist for example, mask ventilation, uncuffed endotracheal tubes, and miniature endotracheal tubes. These devices frequently cause leakage of gases such that measurement of flow and volume become erroneous.

Current technology is therefore often limited in its ability to detect and correct for these gas leaks and patients are at risk of becoming hyper- or hypo-ventilated.

OBJECTS OF THE INVENTION

An object of the present invention is therefore to overcome the above described drawbacks of the prior art.

Another object of the present invention is to provide a method and a device capable of adjusting the degree of inspiratory assist in relation to the real need of the patient, i.e. only to compensate for the degree of incapacity of the patient.

A further object of the present invention is to provide a method and a device for controlling inspiratory proportional pressure assist ventilation which requires no knowledge of the elastic and viscous properties of the patient's respiratory system, is not influenced by intrinsic positive end-expiratory pressure, altered muscle function, and is not

influenced by air leakage of the lung ventilator unless the leakage exceeds the pumping capacity of the ventilator.

SUMMARY OF THE INVENTION

More specifically, in a preferred embodiment of the invention, there is provided a gain controller for adjusting, in relation to a target drive signal, the value of a gain applied to a signal representative of respiratory drive output of a patient during inspiration, to produce an amplified respiratory drive output representative signal for controlling a lung ventilator assisting inspiration of the patient. The gain controller comprises:

a first input for receiving the signal representative of respiratory drive output having a first amplitude;

a second input for receiving the target drive signal of a second amplitude;

a comparator for determining whether the amplitude of the signal representative of respiratory drive output is higher or lower than the amplitude of the target drive signal; and

a gain adjustment unit for increasing the value of the gain when the amplitude of the signal representative of respiratory drive output is higher than the amplitude the target drive signal and for decreasing the value of the gain when the amplitude of the signal representative of respiratory drive output is lower than the amplitude of the target drive signal.

In another embodiment of the invention, there is provided a method for adjusting, in relation to a target drive signal, the

value of a gain applied to a signal representative of respiratory drive output of a patient during inspiration, to produce an amplified respiratory drive output representative signal for controlling a lung ventilator assisting inspiration of the patient. The method comprises:

receiving the signal representative of respiratory drive output having a first amplitude;

receiving the target drive signal of a second amplitude;

determining whether the amplitude of the signal representative of respiratory drive output is higher or lower than the amplitude of the target drive signal; and

increasing the value of the gain when the amplitude of the signal representative of respiratory drive output is higher than the amplitude of said target drive signal; and decreasing the value of the gain when the amplitude of the signal representative of respiratory drive output is lower than the amplitude of the target drive signal.

Target drive ventilation is based on the assumption that the patient's respiratory centers are intact and the patient is able to control minute ventilation as long as he/she has sufficient respiratory muscle. In a preferred embodiment of the invention, determination of respiratory drive is made by measuring the electrical activation of the diaphragm during an inspiration. Of course, any other signal representative of respiratory drive output may be used in other embodiments of the invention. Electrical activity of the diaphragm has previously been demonstrated to reflect global respiratory drive. The inspiratory electrical activation of the diaphragm can be quantified as the mean, median, total, peak, etc. and the trend of the previous breaths is used to adjust ventilatory assist for the present breath.

The invention is aimed to control ventilatory assist levels in order to maintain the respiratory drive (determined by diaphragm electric activation) at a sustainable target level. The lung ventilator can use a pressure/flow/volume generating device with a control unit which operates to maintain the mean (could also be median/peak/total, etc.) pressure/flow/volume in the ventilatory line sufficient for maintaining a constant target diaphragm electrical activity. The diaphragm electrical activity during a breath will be calculated in order to determine the mean (could also be median/peak/total, etc.) neural drive to the diaphragm for that particular breath. The trend for respiratory drive can be obtained from diaphragm electrical activity of previous breaths such that one can determine whether respiratory drive increases, decreases, or remains constant. A trend for a change in diaphragm electrical activity indicating an increase in respiratory drive will result in a progressive increase ventilatory assist until diaphragm electrical activity, i.e., respiratory drive has returned to its target level. Similarly, the decrease in diaphragm electrical activity, indicating reduced respiratory drive, will produce a progressive decrease in ventilatory assist until diaphragm electrical activity i.e.respiratory drive has returned to its target level.

Target Drive Ventilation would be more efficiently used in combination with Neurally Adjusted Proportional Pressure Assist (US patent no. 5,820,560 to Sinderby et al., 1998), where ventilatory assistance will be proportional to the patient's respiratory drive throughout the breath and the average respiratory drive would remain constant over time. For proportional assist ventilation or other modes which deliver varying levels of support, the increasing or decreasing levels of mean/total ventilatory assist will be adjusted by increasing or decreasing the gain factor applied in the respective functions.

Target drive ventilation can also be applied with other modes of ventilatory assist. For use with ventilatory support modes that provide constant levels of support, for example pressure support, the increasing or decreasing levels of mean/total ventilatory assist will be achieved by relative increases or decreases of the pressure support, the increasing or decreasing levels of mean/total ventilatory assist will be achieved by relative increases or decreases of the pressure support level. Extreme pressure support levels will be avoided by introducing safety limits.

The advantage of Target drive ventilation is that this mode of ventilation does not depend on flow or volume measurements. A leaky ventilatory line will introduce a change in respiratory drive which will change the ventilatory assist in order to return the respiratory drive to its target level. Also, changes in the patient's metabolic or patho-physiological status which result in altered respiratory drive will be compensated. In contrast with present methods of controlling mechanical ventilators, an increase in respiratory assistance using a signal representative of respiratory drive output (e.g., an EMG signal) does not affect the efficiency with which these signals reliably control the ventilator (unless of course the disease affects the neuro-muscular function).

A combination of Target Drive Ventilation and Neurally Adjusted Proportional Pressure Assist (US patent no. 5,820,560), would provide partial correction for leaks within breaths and compensation for leaks over long periods of time. The use of neural triggers would also overcome issues related to intrinsic PEEP.

The objects, advantages and other features of the present invention will become more apparent upon reading of the following non

restrictive description of a preferred embodiment thereof, given by way of example only with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the appended drawings:

Figure 1 is a schematic representation of a set-up of an EMG analysis system;

Figure 2 is a section of oesophageal catheter on which an array of electrodes of the EMG analysis system of Figure 1 is mounted;

Figure 3 illustrates a section of oesophageal catheter on which a second embodiment of the array of electrodes is mounted;

Figure 4 is a graph showing a set of EMGdi signals of the diaphragm detected by pairs of successive electrodes of the array of Figure 2;

Figure 5A is a flow chart showing a method for conducting double subtraction technique of the EMGdi signals;

Figure 5B is a flow chart showing a method for controlling a gain value in accordance with an embodiment of the invention;

Figure 6 is a graph showing the distribution of correlation coefficients calculated for determining the position of the center of the

depolarizing region of the diaphragm along the array of electrodes of Figure 2;

Figure 7 is a schematic diagram illustrating in the time domain a double subtraction technique for improving the signal-to-noise ratio and to reduce an electrode-position-induced filter effect;

Figure 8a is a graph showing the power density spectrum of electrode motion artifacts, the power density spectrum of ECG, and the power density spectrum of EMGdi signals;

Figure 8b is a graph showing an example of transfer function for a filter to be used for filtering out the electrode motion artifacts, ECG, and the 50 or 60 Hz disturbance from electrical mains;

Figure 9 is a schematic diagram illustrating in the frequency domain stabilization by the double subtraction technique of the center frequency upon displacement of the center of the depolarizing region of the diaphragm along the array of electrodes of Figure 2;

Figure 10 is a schematic block diagram of a lung ventilator showing control of inspiratory proportional pressure assist ventilation by means of an EMG signal obtained with the above mentioned double subtraction technique; and

Figure 11 is a schematic block diagram showing a structure for implementing the steps of the method described in Figure 5B.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

To measure EMG activity of the diaphragm 11 (EMGdi) of a human patient 14, an array of electrodes such as 12 (Figures 1 and 2) are mounted on the free end section 15 of an oesophageal catheter 13, with a constant inter-electrode distance **d** (Figure 2). As shown in Figure 1, the catheter 13 is introduced into the patient's oesophagus through one nostril or the mouth until the array of electrodes 12 are situated at the level of the gastro esophageal junction. The diaphragm 11 and/or the oesophagus slightly move during breathing of the patient 14 whereby the array of electrodes 12 also slightly moves about the diaphragm 11. As will be explained in the following description, automatic compensation for this displacement is provided.

To mount an electrode 12 on the free end section 15 of the catheter 13, stainless steel wire (not shown) may be wound around the catheter 13. The wound stainless steel wire presents a rough surface smoothed out by solder, which in turn is electroplated with nickel, copper and then gold or silver. Of course, EMG signals from other muscles and other constructions of electrodes can be implemented.

Electric wires (not shown) interconnect each pair of successive electrodes such as 1-7 (Figure 2) with a respective one of a group of differential amplifiers 16. This defines an overlap array. Obviously, these electric wires follow the catheter 13 from the respective electrodes 12 to the corresponding amplifiers 16, and are preferably integrated to the catheter 13. Preferably, the electric wires transmitting the EMGdi signals collected by the various pairs 1-7 of electrodes 12 are shielded to reduce

the influence of external noise, in particular disturbance from the 50 or 60 Hz current and voltage of the electrical mains.

The group of differential amplifiers 16 amplifies (first subtraction step of the double subtraction technique) and band-pass filters each EMGdi signal. This first subtraction step may also be carried out in the personal computer 19 when the amplifiers 16 are single-ended or equivalently designed amplifiers (monopolar readings).

In the example illustrated in Figures 1 and 2, the free end section 15 of the catheter 13 is provided with an array of eight electrodes 12 defining seven pairs 1, 2, 3, 4, 5, 6 and 7 of successive electrodes 12 respectively collecting seven different EMGdi signals. Although it has been found that EMG activity of the diaphragm (EMGdi) can be measured accurately with an oesophageal catheter 13 provided on the free end section 15 thereof with an array of eight electrodes 12, a different number and/or configuration of pairs of electrodes 12 can be contemplated depending on the patient's anatomy and movement of the diaphragm. Also, the pairs 1-7 do not need to be pairs of successive electrodes; Figure 3 illustrates an array of nine electrodes to form seven overlapping pairs of electrodes 1-7.

A major problem in recording EMGdi signals is to maintain the noise level as low and as constant as possible. Since the electric wires transmitting the EMGdi signals from the electrodes 12 to the differential amplifiers 16 act as an antenna, it is crucial, as indicated in the foregoing description, to shield these electric wires to thereby protect the EMGdi signals from additional artifactual noise. Also, the package enclosing the differential amplifiers 16 is preferably made as small as possible

(miniaturized) and is positioned in close proximity to the patient's nose to decrease as much as possible the distance between the electrodes 12 and the amplifiers 16.

The amplified EMGdi signals are supplied to a personal computer 19 through respective isolation amplifiers of a unit 18. Unit 18 supplies electric power to the various electronic components of the differential and isolation amplifiers while ensuring adequate isolation of the patient's body from such power supply. The unit 18 also incorporates bandpass filters included in the respective EMGdi signal channels to eliminate the effects of aliasing. The EMGdi signals are then digitally processed into the personal computer 19 after analog-to-digital conversion thereof. This analog-to-digital conversion is conveniently carried out by an analog-to-digital converter implemented in the personal computer 19. The personal computer 19 includes a monitor 40 and a keyboard 31.

It is believed to be within the capacity of those of ordinary skill in the art to construct suitable differential amplifiers 16 and an adequate isolation amplifiers and power supply unit 18. Accordingly, the amplifiers 16 and the unit 18 will not be further described in the present specification.

An example of the seven EMGdi signals collected by the pairs 1-7 of successive electrodes 12 (Figures 1 and 2) and supplied to the computer 19 is illustrated in Figure 4.

As the diaphragm is generally perpendicular to the longitudinal axis of the oesophageal catheter 13 equipped with an array of electrodes 12, only a portion of the electrodes 12 are situated in the vicinity of the

diaphragm. It is therefore important to determine the position of the diaphragm with respect to the oesophageal electrode array.

The portion of the crural diaphragm 11 which forms the muscular tunnel through which the oesophageal catheter 13 is passed is referred to the "diaphragm depolarizing region" (DDR). The thickness of the DDR is 20-30 mm. It can be assumed that, within the DDR, the distribution of active muscle fibers has a center from which the majority of the EMGdi signals originate, i.e. the "diaphragm depolarizing region center" (DDR center). Therefore, EMGdi signals detected on opposite sides of the DDR center will be reversed in polarity with no phase shift; in other words, EMGdi signals obtained along the electrode array are reversing in polarity at the DDR center.

Moving centrally from the boundaries of the DDR, EMGdi power spectrums progressively attenuate and enhance in frequency. Reversal of signal polarity on either side of the electrode pair 4 with the most attenuated power spectrum confirms the position from which the EMGdi signals originate, the DDR center.

Referring to Figure 5A, the first task of the computer 19 is to determine the center of the DDR. The center of the DDR is repeatedly determined at predetermined time intervals.

For that purpose, slow trend is first removed from each EMGdi signal (step 500). To carry out such trend removal, the processing conducted by the computer 19 on each EMGdi signal is equivalent to high-pass filtering each EMGdi signal at a transition frequency of about 20 Hz. In particular, step 500 will remove the direct current component

of the EMGdi signals to enable the computer 19 to evaluate the polarities of the EMGdi signals relative to each other.

In step 501, the EMGdi signals are cross-correlated in pairs. As well known to those of ordinary skill in the art, cross-correlation is a statistical determination of the phase relationship between two signals and essentially calculates the similarity between two signals in terms of a correlation coefficient **r** (step 502). A negative correlation coefficient **r** indicates that the cross-correlated signals are of opposite polarities.

Figure 6 shows curves of the value of the correlation coefficient **r** versus the midpoint between the pairs of electrodes from which the correlated EMGdi signals originate. In this example, the inter-electrode distance is 10 mm. Curves are drawn for distances between the correlated pairs of electrodes 12 of 5 mm (curve 20), 10 mm (curve 21), 15 mm (curve 22) and 20 mm (curve 23). One can appreciate from Figure 5A that negative correlation coefficients **r** are obtained when EMGdi signals from respective electrode pairs situated on opposite sides of the electrode pair 4 are cross-correlated. It therefore appears that the change in polarity occur in the region of electrode pair 4, which is confirmed by the curves of Figure 4. Accordingly, it can be assumed that the center of the DDR is situated substantially midway between the electrodes 12 forming pair 4.

For example, the center of the DDR can be precisely determined by interpolation (step 503 of Figure 5A) using a square law based fit of the three most negative correlation coefficients of curve 21 obtained by successive cross-correlation of the EMGdi signals from each electrode pair to the EMGdi signals from the second next electrode pair.

Association of the center of the DDR to a pair of electrodes 12 provides a "reference position" from which to obtain EMGdi signals within the DDR. Such control is essential in overcoming the artifactual influence on the EMGdi power spectrum.

It has been experimentally demonstrated that EMGdi signals recorded in the oesophagus are satisfactory as long as they are obtained from electrode pairs (with an inter-electrode distance situated between 5 and 20 mm) positioned at a distance situated between 5 and 30 mm on the opposite sides of the DDR center (the inter-pair distance being therefore situated between 5 and 30 mm). Although EMGdi signals obtained from these positions offers a clear improvement in acceptance rate, the signal-to-noise ratio during quiet breathing still tends to remain unsatisfactorily low.

In another embodiment of the invention, step 500 can be eliminated and steps 501, 502 and 503 could be implemented immediately after step 505.

For example, in Figure 4, the EMGdi signals originating from the electrode pairs 3 and 5 situated respectively 10 mm below and 10 mm above the DDR are strongly inversely correlated at zero time delay. In contrast to the inversely correlated EMGdi signals, the noise components for electrode pairs 3 and 5 are likely to be positively correlated. Hence, as illustrated in Figure 7, subtraction of the EMGdi signals 24 and 25 from electrode pairs 3 and 5 will result into an addition of the corresponding EMGdi signals (signal 26 of Figure 6) and into a subtraction, that is an elimination of the common noise components. This technique will be referred to as "the double subtraction technique" (step 504 of Figure 5A).

Subtraction step 504 (second subtraction step of the double subtraction technique) can be carried out either in the time domain, or after conversion of signals 24 and 25 in the frequency domain. Double subtraction technique can be performed by subtracting other combinations of signals, for example by subtracting the EMGdi signal from electrode pair 2 from the EMGdi signal from electrode pair 5 (Figure 4), by subtracting signal from electrode pair 6 from the signal from electrode pair 3 and by adding these differences, etc. Other means for reducing the effect of electrode filtering can be applied.

The double subtraction technique is carried out in step 504 on the pair of EMGdi signals (for example the signals from electrode pairs 3 and 5 shown in Figure 4) identified in step 503, after appropriate filtering of these EMGdi signals in step 505. Filtering step 505 will remove from each EMGdi signal the motion artifacts, the electrocardiogram (ECG) component, and the disturbance from the electrical mains. Motion artifacts are induced by motion of the electrodes. More generally, motion artifacts are defined as a low frequency fluctuation of the EMGdi signals' DC level induced by mechanical alterations of the electrode metal to electrolyte interface i.e. changes in electrode contact area and/or changes in pressure that the tissue exerts on the electrode.

The graph of Figure 8a shows the power density spectrum of the above defined electrode motion artifacts, the power density spectrum of ECG, and the power density spectrum of EMGdi signals. The graph of Figure 8b shows an example of transfer function for a filter (the dashed line showing the optimal transfer function, and the solid line the transfer function implemented by the inventors) to be used in step 505 for filtering out the electrode motion artifacts, ECG, and the 50 or 60 Hz disturbance

from the electrical mains. Processing of the EMGdi signals by the computer 19 to follow as closely as possible the optimal transfer function of Figure 8b will conduct adequately filtering step 505.

Referring back to Figure 5A, step 506 calculates the RMS (Root-mean-square) value of the double-subtracted signal produced in step 504. The increase in amplitude obtained with the double subtraction technique is associated with a twofold increase in RMS values. RMS values obtained with the double subtraction technique are closely and linearly related to the original signals. The RMS value can be replaced by any other value representative of the strength of the double-subtracted signal, for example mean, median, peak or total signal amplitudes.

The double subtraction technique compensates for the changes in signal strength and frequency caused by movement of the diaphragm 11 (Figure 1) and/or the oesophagus during breathing of the patient 14 causing movement of the array of electrodes 12 with respect to the diaphragm 11. Referring to Figure 9, off center of the array of electrodes 12 (electrode-position-induced filter effect) causes a variation of center frequency values (see curves 27 and 28) for the EMGdi signals from the electrode pairs 3 and 5. The double subtraction technique eliminates such variation of center frequency values as indicated by curve 29 as well as variation of signal strength. Therefore, the reciprocal influence of the position of the DDR center on the EMGdi signal frequency content is eliminated by the double subtraction technique.

It has been found that the double subtraction technique may improve the signal-to-noise ratio by more than 2 dB ratio and reduce an electrode-position-induced filter effect. Double subtraction technique is

also responsible for a relative increase in acceptance rate by more than 30%.

Cross-talk signals from adjacent muscles are strongly correlated at zero time delay and equal in polarity between all pairs of electrodes 12. Hence, these cross-talk signals appear as a common mode signal for all electrode pairs and therefore, are eliminated by the double subtraction technique.

Referring to Figure 5B, a target drive signal is set by an operator at step 601. The output of block 601 is therefore the target drive signal 602. The value of the target drive signal 602 is determined by a person skilled in the art. The target drive signal 602 can be any signal which is representative of respiratory drive output. In a preferred embodiment of the invention, this signal can be any signal representative of the electrical activity of a muscle (i.e., electromyographic signal) that reflects the global respiratory drive. The target drive signal 602 can therefore be quantified as, among others, the mean, the median, the total or the peak of the EMGdi signal. The target drive signal 602 is then compared to the RMS value on line 508 in block 604. If the present breath RMS value on line 508 is greater than the target drive signal 602, this indicates that there is a trend for a change in diaphragm electrical activity (EMGdi) indicating an increase in respiratory drive and requiring a progressive increase in ventilatory assistance. The result of the decision block 604 will be positive until the EMGdi 508 returns to the target level 602. In this case, the stored gain (k) will be increased in block 606. The gain (k) 610 will then be recorded in block 611 and outputted as signal 613.

Returning now to block 604, if the present breath RMS value on line 508 is not greater than the target drive signal 602, it may be equal or smaller. In block 605, it is determined if the present breath RMS value 508 is equal to the target drive signal 602. If it is equal, the gain value (k) does not change.

If the present breath RMS value 508 is not equal to the target drive signal 602, then it is smaller than the target drive signal 602, and this indicates a decrease in diaphragm electrical activity (EMGdi) resulting in reduced respiratory drive. It will therefore be necessary to progressively decrease the ventilatory assist until the diaphragm electrical activity (EMGdi) 508 returns to the target level 602. In this case, the result from decision block 604 will be negative resulting in a decrease in the stored gain (k) in block 608. The gain (k) 609 will then be stored at step 611 and outputted as signal 613.

Those skilled in the art will understand that the amount of the change (increase, step 606, or decrease, step 608) in ventilatory assistance is derived from experience, the patient's condition, the environment, etc. The amount of change can therefore be adjusted on a case by case basis. Also, in a particular embodiment of the invention, the increase or decrease in ventilatory assistance could be a relative value; that is, a fraction or percentage multiplied by, for example, the target drive signal, the signal representative of respiratory drive output, or a difference between the amplitude of the signal representative of respiratory drive output and the amplitude of the target drive signal.

Those skilled in the art will also understand that the test at steps 604 and 605 can include a certain range of amplitudes for the target drive

signal 602 (whether they are absolute or relative amplitudes); that is, for example, the target drive signal could be X plus or minus a predetermined value. Therefore, at step 604, the present breath RMS value 508 needs to be greater than X plus the predetermined value in order to proceed to step 606. In the same way, at step 605, the present breath RMS value 508 needs to be smaller than X minus the predetermined value in order to proceed to step 608.

Finally, the present RMS value on line 508 will be multiplied by the gain (k) 613 in block 612 to produce a control signal 614. The control signal 614 will be the input to lung ventilator 54 of Figure 10.

Figure 11 illustrates a possible physical embodiment of steps 604, 605, 606, 608, 611, and 612 of Figure 5B. A gain controller 620 and a gain multiplier 628 are provided. A first input to gain controller 620 is the RMS value on line 508, a second input to gain controller 620 is target drive signal 602, and the output of gain controller 620 is gain (k) 613 value. The gain (k) 613 value is then inputted to the gain multiplier 628 where it is multiplied by the RMS value on line 508 for the present inspiration (step 612 of Figure 5B) resulting in a control signal 614.

The gain controller 620 further comprises a comparator 624 and a gain adjustment block 626. The comparator 624 implements steps 604 and 605 and the gain adjustment block 626 implements steps 606, 608 and 611 of Figure 5B.

Figure 10 illustrates a lung ventilator 54 capable of being controlled by the multiplied, RMS value 614 of the double-subtracted signal produced in step 612 of Figure 5B. Although an air-flow-based

pressure ventilator is illustrated as an example in Figure 10, it should be kept in mind that the RMS value of the double subtracted signal can be used for controlling any other lung ventilator.

Ventilator 54 shown in Figure 10 as an illustrative example only comprises a flow control unit 53, a flow pump 55, a patient's respiratory (inspiratory and expiratory) implement 56 such as a mask, a tracheal tube connector, or any other respiratory implement, a pressure sensor 57, a pressurizing valve 58, and a depressurizing valve 59.

The flow pump 55 produces a constant air flow and supply of this air flow to the patient's respiratory accessory 56 is controlled through the pressurizing valve 58. The patient is allowed to breathe out through the respiratory accessory 56 and the depressurizing valve 59. The pressurizing and depressurizing valves 58 and 59 are controlled by the flow control unit 53.

The pressure sensor 57 is connected close to the respiratory implement 56 through a line 60. The pressure sensor 57 produces a corresponding respiratory pressure representative signal 61 supplied to the flow control unit 53. Accordingly, the pressure sensor 57 provides feedback of actual respiratory pressure close to the respiratory implement 56. The flow control unit 53 is also supplied with the multiplied, RMS value 614 of the double-subtracted signal delivered on line 62 (Figure 10) by step 612 of Figure 5B.

Those of ordinary skill in the art know that the amplitude of the multiplied, RMS value 614 of the double-subtracted signal delivered on line 62 is a representation of the demand to breathe from the brain.

When the RMS value 614 supplied to the flow control unit 53 is higher than the amplitude of the pressure representative signal 61, this indicates that the demand to breath from the brain is higher than the air actually breathed by the patient. Inspiratory assist is then required and the flow control unit 53 will open pressurizing valve 58 to supply air flow from the pump 55 to the patient's respiratory accessory (depressurizing valve 59 being closed) until the amplitude of the pressure representative signal 61 is equal to the multiplied, RMS value 614. The flow control unit 53 will continue to control the position of valve 58 to maintain the amplitude of the pressure representative signal 61 equal to the multiplied, RMS value 614 during all the inspiratory cycle.

During the inspiratory cycle, when the multiplied, RMS value 614 falls slightly below the amplitude of the pressure representative signal 61, depressurizing valve 59 can be opened to correct the situation and maintain the amplitude of the pressure representative signal 61 equal to the multiplied, RMS value 614.

When the multiplied, RMS value 614 drops below a given threshold, this indicates the beginning of an expiratory cycle. Then, the flow control unit 53 closes pressurizing valve 58 and opens depressurizing valve 59 to allow the patient to breath out through the respiratory accessory 56 and the depressurizing valve 59.

In another example embodiment of the invention, in order to obtain correct proportionality between the pressure representative signal 61 and the multiplied, RMS value 614, a gain adjustment is introduced for example in sensor 57 or on the line 62 to adequately control pressure

assist to the respiratory implement 56 in function of the multiplied, RMS value 614.

Accordingly, the subject invention presents a major advantage over the prior art. Indeed, the degree of inspiratory assist is adjusted in relation to the real need of the patient. In other words, assist is proportional to the difference between the pressure representative signal 61 and the multiplied, RMS value 614. Inspiratory assist is therefore provided only to compensate for the degree of incapacity of the patient. The patient still contributes to inspiration as a function of his capacity to prevent the lung ventilator to further reduce the patient's inability to breathe. Requiring breathing efforts from the patient usually accelerates recovery of the patient and faster disconnection of the patient from the lung ventilator.

Although the present invention has been described herein above with reference to preferred embodiments thereof, these embodiments can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the subject invention.

WHAT IS CLAIMED IS:

1. A gain controller for adjusting, in relation to a target drive signal, the value of a gain applied to a signal representative of respiratory drive output of a patient during inspiration, to produce an amplified respiratory drive output representative signal for controlling a lung ventilator assisting inspiration of the patient, said gain controller comprising:

a first input for receiving the signal representative of respiratory drive output having a first amplitude;

a second input for receiving the target drive signal of a second amplitude;

a comparator for determining whether the amplitude of said signal representative of respiratory drive output is higher or lower than the amplitude of said target drive signal; and

a gain adjustment unit for increasing the value of said gain when the amplitude of said signal representative of respiratory drive output is higher than the amplitude of said target drive signal and for decreasing the value of said gain when the amplitude of the signal representative of respiratory drive output is lower than the amplitude of the target drive signal.

2. A gain controller as recited in claim 1, wherein said target drive signal comprises a range of amplitudes.

3. A gain controller as recited in claim 2, comprising means for expressing the increase or the decrease in the value of said gain as a fraction.

4. A gain controller as recited in claim 3, further comprising a means for adjusting said target drive signal by said fraction to obtain an amount of change of the value of said gain.

5. A gain controller as recited in claim 3, further comprising a multiplier for multiplying said target drive signal by said fraction to obtain an amount of change of the value of said gain.

6. A gain controller as recited in claim 3, further comprising a multiplier for multiplying said signal representative of respiratory drive output by said fraction to obtain an amount of change of the value of said gain.

7. A gain controller as recited in claim 3, further comprising:

a subtractor for calculating a difference between the amplitude of said signal representative of respiratory drive output and the amplitude of said target drive signal; and

a multiplier for multiplying said difference by said fraction to obtain an amount of change of the value of said gain.

8. A gain controller as recited in claim 1, wherein said signal representative of respiratory drive output comprises an electromyographic signal from at least one muscle of the patient.

9. A gain controller as recited in claim 8, wherein said at least one muscle comprises a diaphragm.

10. A gain controller as recited in claim 8, further comprising an array of electrodes for detecting said electromyographic signal.

11. A gain controller as recited in claim 10, wherein said array of electrodes is a linear array of electrodes.

12. A gain controller as recited in claim 1, comprising means for expressing said signal representative of respiratory drive output and said target drive signal as mean signal amplitudes.

13. A gain controller as recited in claim 1, comprising means for expressing said signal representative of respiratory drive output and said target drive signal as median signal amplitudes.

14. A gain controller as recited in claim 1, comprising means for expressing said signal representative of respiratory drive output and said target drive signal as peak signal amplitudes.

15. A gain controller as recited in claim 1, comprising means for expressing said signal representative of respiratory drive and said target drive signal as total signal amplitudes.

16. A gain controller as recited in claim 1, wherein said lung ventilator comprises a pressure generating device.

17. A gain controller as recited in claim 1, wherein said lung ventilator comprises a flow generating device.

18. A gain controller as recited in claim 1, wherein said lung ventilator comprises a volume generating device.

19. A method for adjusting, in relation to a target drive signal, the value of a gain applied to a signal representative of respiratory drive output of a patient during inspiration, to produce an amplified respiratory drive output representative signal for controlling a lung ventilator assisting inspiration of the patient, said method comprising:

receiving the signal representative of respiratory drive output having a first amplitude;

receiving the target drive signal of a second amplitude;

determining whether the amplitude of said signal representative of respiratory drive output is higher or lower than the amplitude of said target drive signal; and

increasing the value of said gain when the amplitude of said signal representative of respiratory drive output is higher than the amplitude of said target drive signal; and decreasing the value of said gain when the amplitude of said signal representative of respiratory drive output is lower than the amplitude of said target drive signal.

20. A method for adjusting the value of a gain as recited in claim 19, wherein said target drive signal comprises a range of amplitudes.

21. A method for adjusting the value of a gain as recited in claim 19, comprising expressing the increase or the decrease in the value of said gain as a fraction.

22. A method for adjusting the value of a gain as recited in claim 21, further comprising adjusting said target drive signal by said fraction to obtain an amount of change of the value of said gain.

23. A method for adjusting the value of a gain as recited in claim 21, further comprising multiplying said target drive signal by said fraction to obtain an amount of change of the value of said gain.

24. A method for adjusting the value of a gain as recited in claim 21, further comprising multiplying said signal representative of respiratory drive output by said fraction to obtain an amount of change of the value of said gain.

25. A method for adjusting the value of a gain as recited in claim 21, further comprising:

calculating a difference between the amplitude of said signal representative of respiratory drive output and the amplitude of said target drive signal; and

multiplying said difference by said fraction to obtain an amount of change of the value of said gain.

26. A method for adjusting the value of a gain as recited in claim 19, wherein said signal representative of respiratory drive output

comprises an electromyographic signal from at least one muscle of the patient.

27. A method for adjusting the value of a gain as recited in claim 26, wherein said at least one muscle comprises a diaphragm.

28. A method for adjusting the value of a gain as recited in claim 26, comprising detecting said electromyographic signal by means of an array of electrodes.

29. A method for adjusting the value of a gain as recited in claim 28, wherein said array of electrodes is a linear array of electrodes.

30. A method for adjusting the value of a gain as recited in claim 19, comprising expressing said signal representative of respiratory drive output and said target drive signal as mean signal amplitudes.

31. A method for adjusting the value of a gain as recited in claim 19, comprising expressing said signal representative of respiratory drive output and said target drive signal as median signal amplitudes.

32. A method for adjusting the value of a gain as recited in claim 19, comprising expressing said signal representative of respiratory drive output and said target drive signal as peak signal amplitudes.

33. A method for adjusting the value of a gain as recited in claim 19, comprising expressing said signal representative of respiratory drive output and said target drive signal as total signal amplitudes.

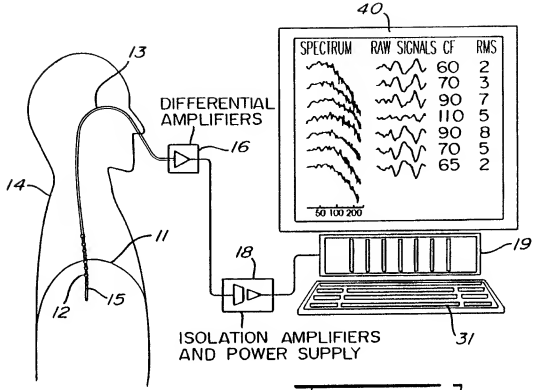
40
SPECTRUM
RAW SIGNALS
CF
RMS
60 2
70 3
90 7
110 5
90 8
70 5
65 2
50 100 200
13
DIFFERENTIAL AMPLIFIERS
16
14
11
18
19
12
15
ISOLATION AMPLIFIERS AND POWER SUPPLY
31

FIG. 1

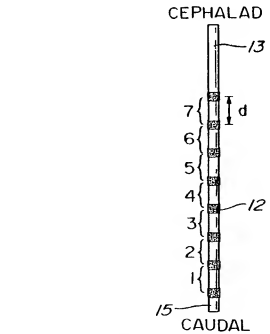
CEPHALAD
13
7
6
5
4
3
2
1
d
12
15
CAUDAL

FIG. 2

CEPHALAD
CAUDAL
1
2
3
4
5
6
7

Fig. 3

VOLTAGE (a.u.)
1
2
3
4
5
6
7
0
50
100
150
200
250
TIME (msec)

Fig. 4

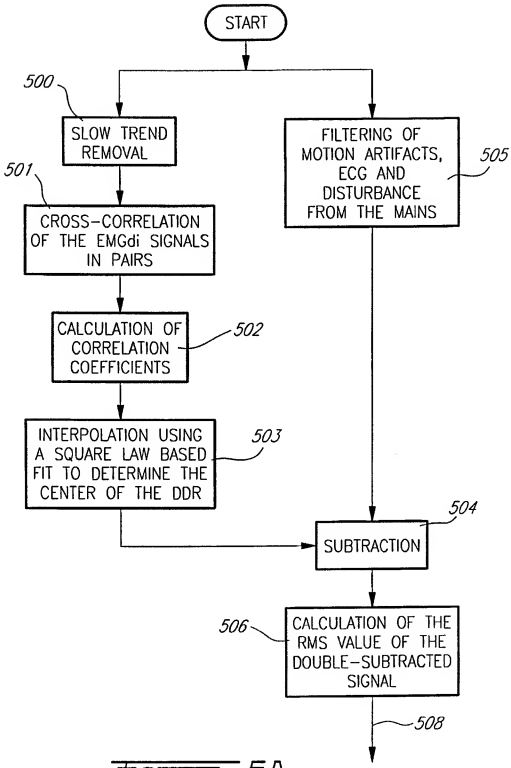
START
500
SLOW TREND REMOVAL
501
CROSS-CORRELATION OF THE EMGdi SIGNALS IN PAIRS
CALCULATION OF CORRELATION COEFFICIENTS
502
INTERPOLATION USING A SQUARE LAW BASED FIT TO DETERMINE THE CENTER OF THE DDR
503
FILTERING OF MOTION ARTIFACTS, ECG AND DISTURBANCE FROM THE MAINS
505
504
SUBTRACTION
506
CALCULATION OF THE RMS VALUE OF THE DOUBLE-SUBTRACTED SIGNAL
508

FIG. 5A

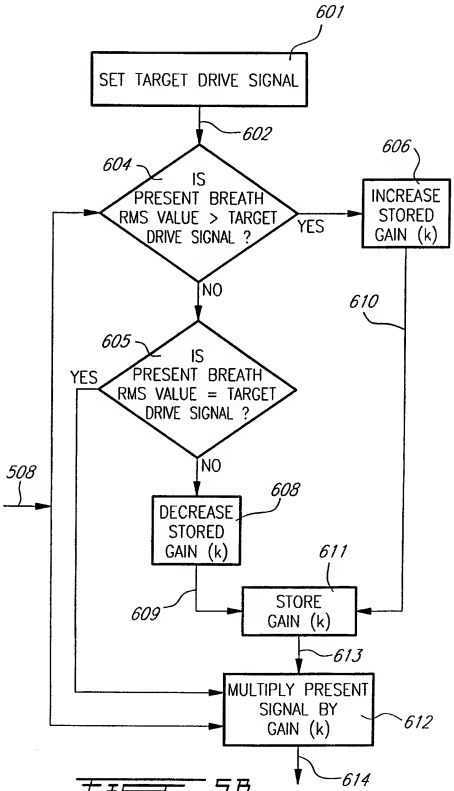
601
SET TARGET DRIVE SIGNAL
602
604
IS PRESENT BREATH RMS VALUE > TARGET DRIVE SIGNAL ?
YES
606
INCREASE STORED GAIN (k)
NO
610
605
IS PRESENT BREATH RMS VALUE = TARGET DRIVE SIGNAL ?
YES
NO
508
608
DECREASE STORED GAIN (k)
611
609
STORE GAIN (k)
613
MULTIPLY PRESENT SIGNAL BY GAIN (k)
612
614

Fig. 5B

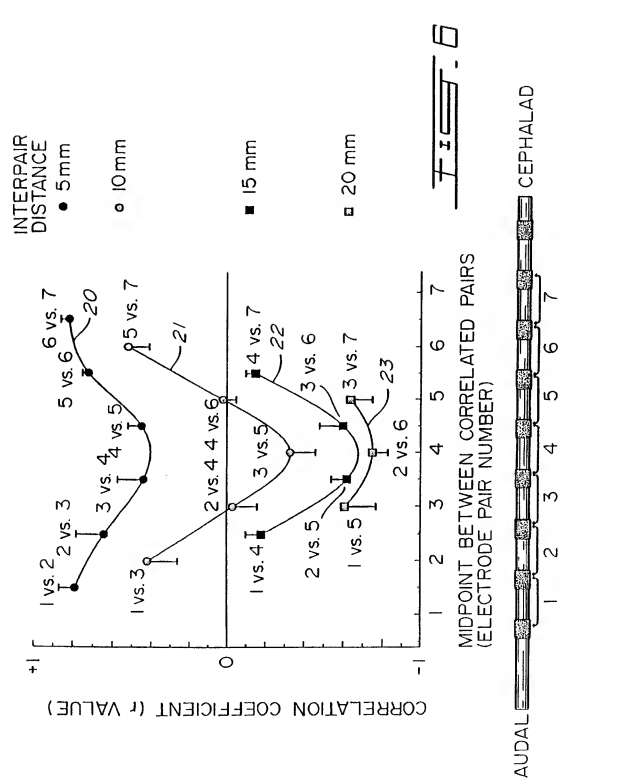
INTERPAIR DISTANCE
5 mm
10 mm
15 mm
20 mm
CORRELATION COEFFICIENT (r VALUE)
+1
0
-1
1 vs. 2
2 vs. 3
3 vs. 4
4 vs. 5
5 vs. 6
6 vs. 7
20
1 vs. 3
2 vs. 4
3 vs. 5
4 vs. 6
5 vs. 7
21
1 vs. 4
2 vs. 5
3 vs. 6
4 vs. 7
22
1 vs. 5
2 vs. 6
3 vs. 7
23
1 2 3 4 5 6 7
MIDPOINT BETWEEN CORRELATED PAIRS
(ELECTRODE PAIR NUMBER)
CAUDAL
CEPHALAD
1 2 3 4 5 6 7

FIG. 6

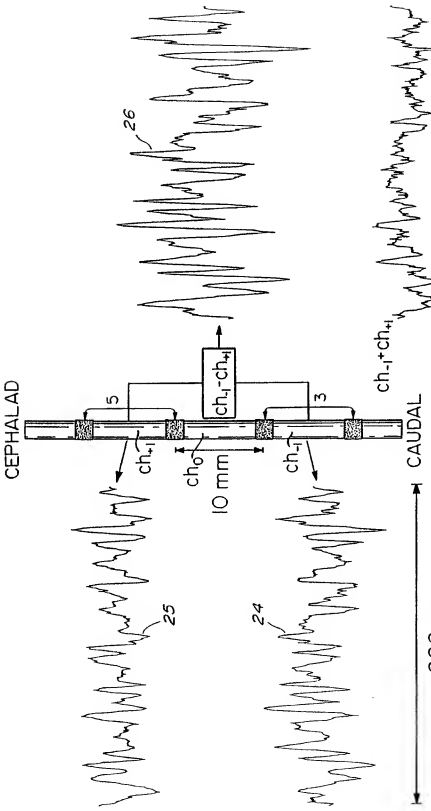
CEPHALAD
CAUDAL
5
3
ch_{+1}
ch_0
ch_{-1}
10 mm
$ch_{+1}-ch_{-1}$
$ch_{-1}+ch_{+1}$
26
25
24
200 ms

FIG-7

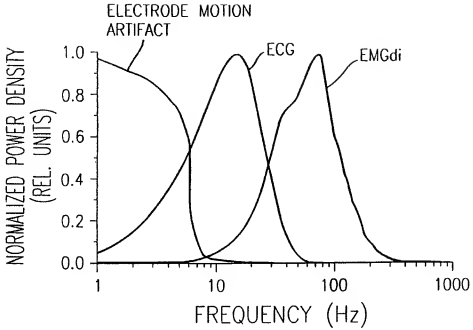
ELECTRODE MOTION ARTIFACT
ECG
EMGdi
NORMALIZED POWER DENSITY (REL. UNITS)
1.0
0.8
0.6
0.4
0.2
0.0
1
10
100
1000
FREQUENCY (Hz)

Fig. 8a

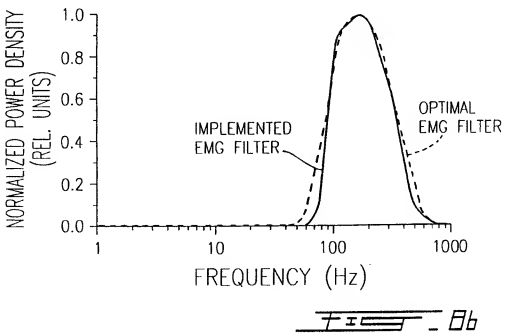
NORMALIZED POWER DENSITY (REL. UNITS)
1.0
0.8
0.6
0.4
0.2
0.0
IMPLEMENTED EMG FILTER
OPTIMAL EMG FILTER
1
10
100
1000
FREQUENCY (Hz)

Fig. 8b

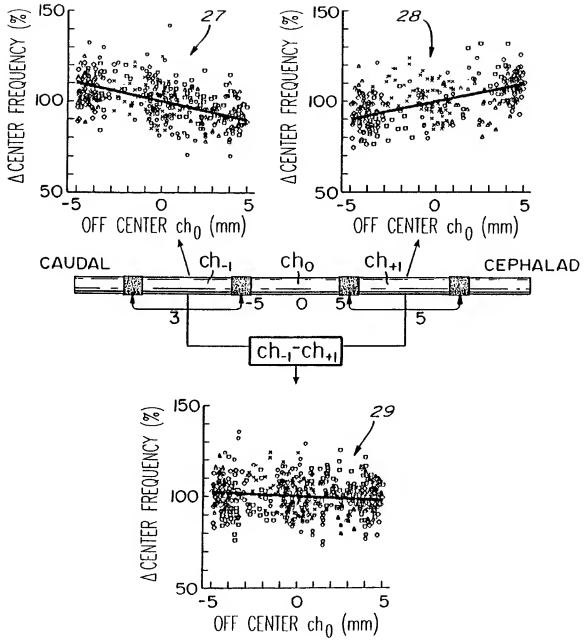
150
100
50
Δ CENTER FREQUENCY (%)
27
-5
0
5
OFF CENTER ch0 (mm)
28
CAUDAL
ch-1
ch0
ch+1
CEPHALAD
3
-5
0
5
5
ch-1-ch+1
29

Fig. 9

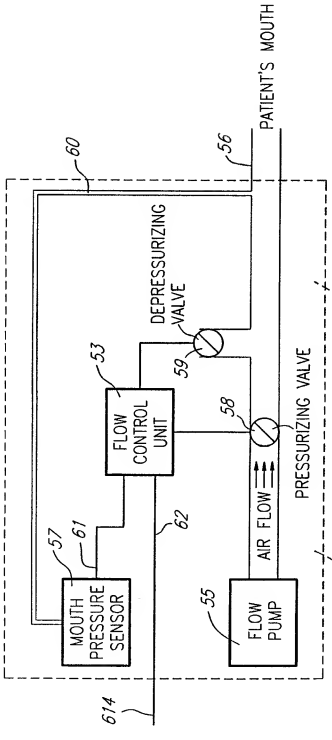
PATIENT'S MOUTH
56
60
DEPRESSURIZING VALVE
59
53
FLOW CONTROL UNIT
58
PRESSURIZING VALVE
54
AIR FLOW
57
61
62
MOUTH PRESSURE SENSOR
55
FLOW PUMP
LUNG VENTILATOR
614

Fig - 10

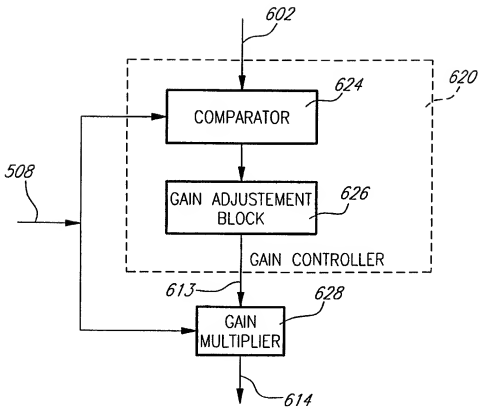
602
620
624
COMPARATOR
508
GAIN ADJUSTEMENT BLOCK
626
GAIN CONTROLLER
613
628
GAIN MULTIPLIER
614

Fig. 11

INTERNATIONAL SEARCH REPORT

Internat ıl Application No
PCT/CA 00/00887

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/00 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 97 22377 A (UNIV MANITOBA ;YOUNES MAGDY (CA)) 26 June 1997 (1997-06-26) page 1, paragraph 2; claims 37,49	1-7 8-18
Y	US 5 820 560 A (SINDERBY CHRISTER ET AL) 13 October 1998 (1998-10-13) cited in the application abstract	8-18
A	US 5 794 615 A (ESTES MARK C) 18 August 1998 (1998-08-18) claims 1,11	1
A	FR 2 596 279 A (BOC SA) 2 October 1987 (1987-10-02)	
A	US 5 890 490 A (AYLSWORTH ALONZO C ET AL) 6 April 1999 (1999-04-06)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 November 2000	30/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax. (+31-70) 340-3016	Villeneuve, J-M

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No
PCT/CA 00/00887

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9722377 A	26-06-1997	AU 1090897 A	14-07-1997
		CA 2240733 A	26-06-1997
		EP 0871509 A	21-10-1998
		JP 11502755 T	09-03-1999
US 5820560 A	13-10-1998	US 5671752 A	30-09-1997
		AU 3534497 A	24-11-1998
		WO 9848877 A	05-11-1998
		EP 0979118 A	16-02-2000
		CA 2172329 A	01-10-1996
US 5794615 A	18-08-1998	US 5535738 A	16-07-1996
		US 6105575 A	22-08-2000
FR 2596279 A	02-10-1987	NONE	
US 5890490 A	06-04-1999	NONE	